Biosecurity Methodology

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DTRA/CTR/BWPP Biosafety and Biosecurity
International Program Review
Budapest, Hungary
March 31, 2004

SAND No. 2004-0323P
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for the United States Department of Energy's National Nuclear Security Administration
under contract DE-AC04-94AL85000.

The Problem: Bioscience Research and International Security

- Increase in awareness of biological weapons and bioterrorist threat
- Recent realization that bioscience research facilities are potential sources of viable and virulent biological agents and toxins
- Yet the bioscience research community has not been accustomed to operating in a security conscious environment
- Research community needs specific tools to achieve a balance between
  - Adequately protecting certain biological agents and toxins
  - Not jeopardizing research on those agents and toxins

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Biosafety vs. Biosecurity

- **Biosafety**
  - **Objective: reduce or eliminate accidental exposure to or release of potentially hazardous agents**
  - **Strategy: implement various degrees of laboratory "containment" or safe methods of managing infectious materials in a laboratory setting**

- **Biosecurity**
  - **Objective: protect biological agents against theft and sabotage**
  - **Strategies**
    - **Prioritize assets based on consequences of loss**
    - **Define unacceptable and acceptable risks by evaluating probabilities and consequences**
    - **Apply a graded protection approach**
    - **Integrate security technologies and procedures across all affected systems**
    - **Impact operations only to the level required**

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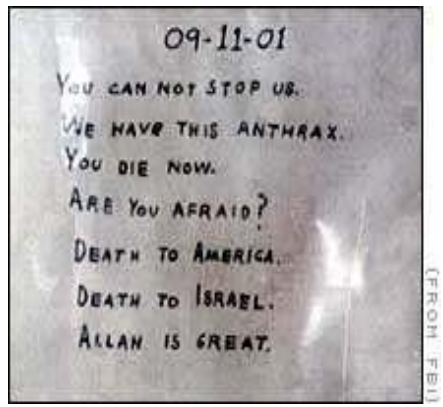
Need to Secure Biological Agents

- Aim of biosecurity is to mitigate biological weapons (BW) threat at the source
  - Prevent terrorists or proliferant states from acquiring biological agents from government, commercial, or academic facilities
- Biosecurity only addresses a small part of the BW threat
  - Biosecurity cannot prevent BW terrorism or proliferation, or even diversion
- Biosecurity is an important element of comprehensive BW nonproliferation program
  - Biosecurity must be augmented by other mechanisms



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General Truisms About Security

- A security system cannot protect every asset against every conceivable threat
- Security resources are not infinite
- Security systems should be based on the asset or material that requires protection
- Security systems should be designed to address unique operations
- Ideally, security should
  - Rely largely on policies and procedures
  - Be transparent to the users
  - Use resources efficiently
  - Not unnecessarily hinder normal operations

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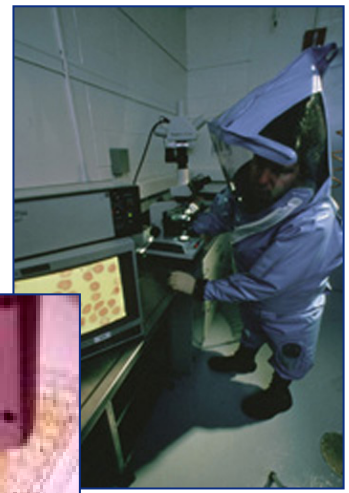
Challenges to Securing Biological Agents

- **Dual-use characteristics**
  - **Valuable for many legitimate, defensive, and peaceful commercial, medical, and research applications**
- **Nature of the material**
  - **Living and self-replicating organisms**
  - **Used in very small quantities**
  - **Cannot be reliably quantified**
  - **Exist in many different process streams in facilities**
  - **Contained biological samples are virtually undetectable using standoff technologies**
- **Laboratory “culture”**
  - **Biological research communities not accustomed to operating in a security conscious environment**



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Biosecurity Cost-Benefit Considerations

- **Bioscience facilities are not unique repositories**
- **Relatively few agents can be easily grown, processed, weaponized, and successfully deployed while maintaining virulence/toxicity**
- **Need a methodology to make informed decisions about how to design an effective and efficient biosecurity system**

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Biosecurity Risk Assessment

1. Define the assets of a facility or group of facilities
2. Evaluate the consequences of the loss of those assets
3. Prioritize the assets based on their consequences of loss
4. Identify the adversaries who would attempt to steal or sabotage those assets
5. Assess the motives and the methods of the adversaries
6. Evaluate the risk (probability and consequences) of those potential undesirable events

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Define the Assets

- Buildings
- Building automation equipment
- Power
- Lab equipment
- Personnel
- Biological agents and toxins
- Information

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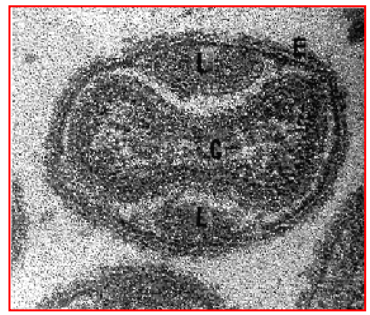
Evaluate Consequences of Loss

- **High consequences**
  - **Loss of asset could directly lead to a national or international security event (e.g., high numbers of casualties, extensive economic damage)**
- **Moderate consequences**
  - **Loss of asset could lead to an event with consequences that do not threaten national or international security**
  - **Loss of asset could assist an adversary in perpetrating a high consequence event or help an adversary gain access to a high consequence asset**
- **Low consequences**
  - **Loss of asset could affect the local operations of an individual facility**



Variola major

Patient's leg covered in smallpox

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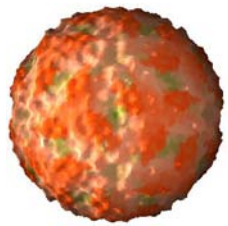
Prioritize Biological Agents

- All biological agents do not need same level of protection
- Prioritize agents based on the consequences of their diversion and their attractiveness to adversaries
  - Infectious disease risk
  - Likelihood agent would be used as a weapon



FMD virus

Yersinia pestis

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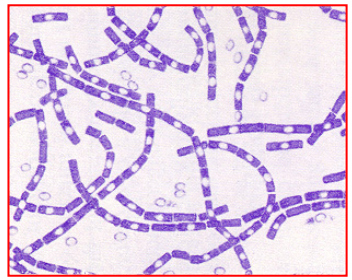
Classify Assets from a Biosecurity Perspective

- **High**
  - **High Consequence Pathogens and Toxins (HCPTs)**
- **Moderate**
  - **Moderate Consequence Pathogens and Toxins (MCPTs)**
  - **Certain information assets**
- **Low**
  - **Low Consequence Pathogens and Toxins (LCPTs)**
  - **Certain facilities, equipment, etc.**



Bacillus anthracis

Castor beans

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Identify Potential Adversaries

- Insider with authorized access
  - Principal investigator
- Invited outsider(s)
  - Visiting scientist
- Outsider(s) with limited access and system knowledge
  - Delivery personnel
- Outsider(s) with no access but has general knowledge
  - Political activist
- Outsider(s) with no access and no general knowledge
  - Psychotic
- Collusion between an insider and an outsider

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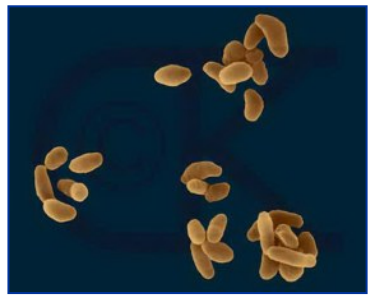
Evaluate Motives and Methods

- **What will the adversaries aim to do?**
  - **Steal, destroy, or disperse agents**
  - **Steal or destroy information**
  - **Steal or destroy equipment**
  - **Destroy operational systems**
  - **Destroy or deface facility**
  - **Injure or kill people**



Francisella tularensis

- **How will the adversaries perpetrate the event?**
  - **Alone or in a group?**
  - **Armed or unarmed?**
  - **Covert or overt?**

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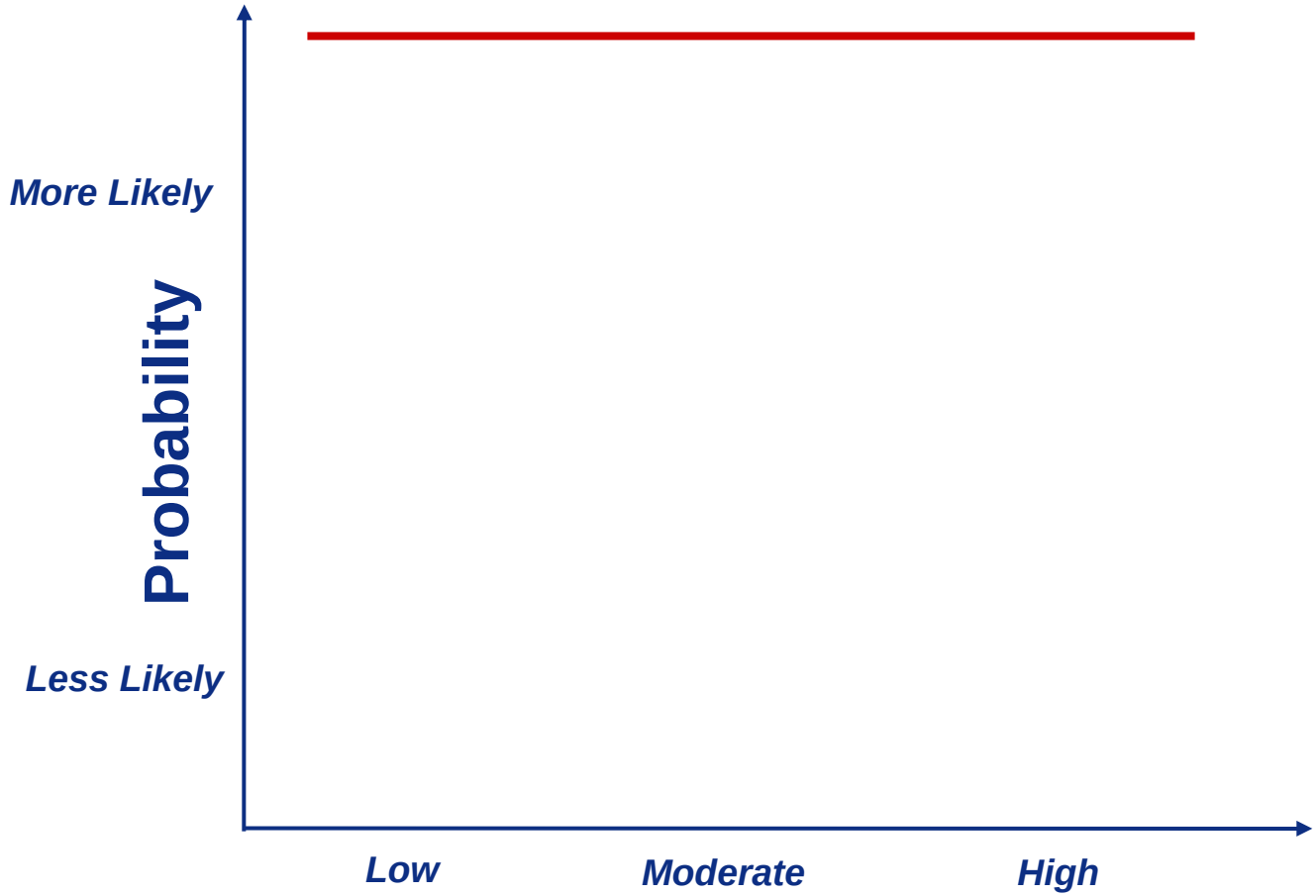
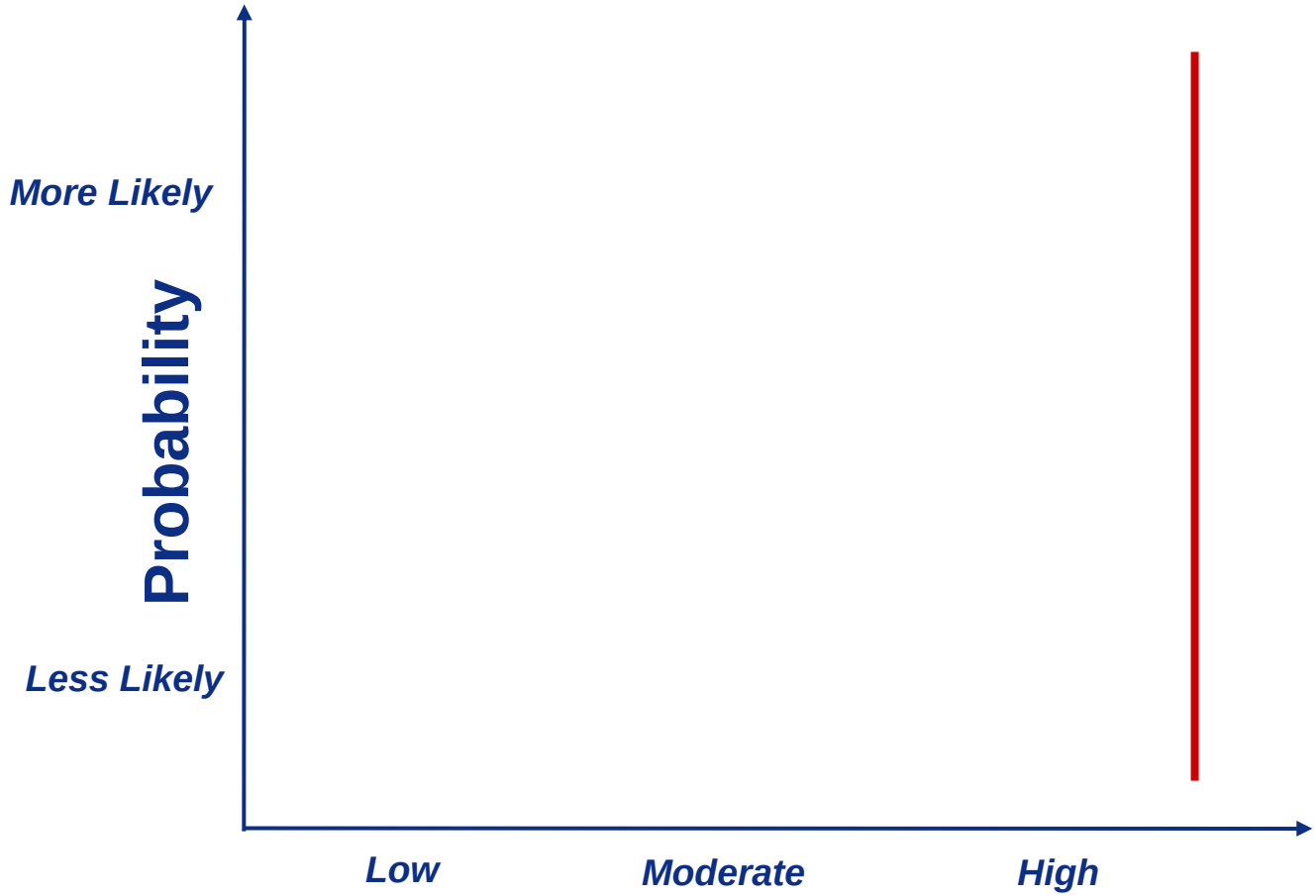
Risk Graph


More Likely
Probability
Less Likely
Low
Moderate
High
Consequences

Risk Graph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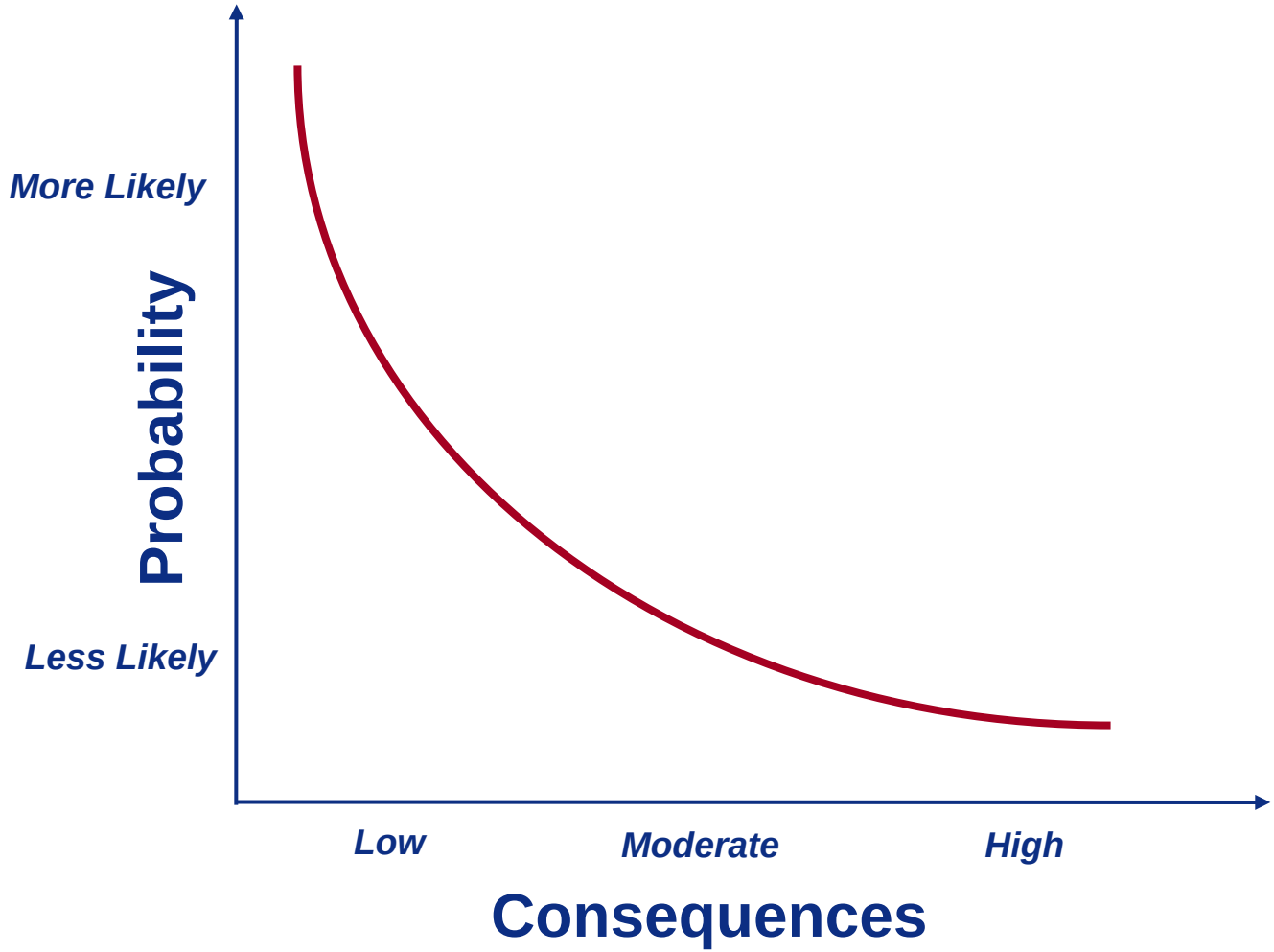
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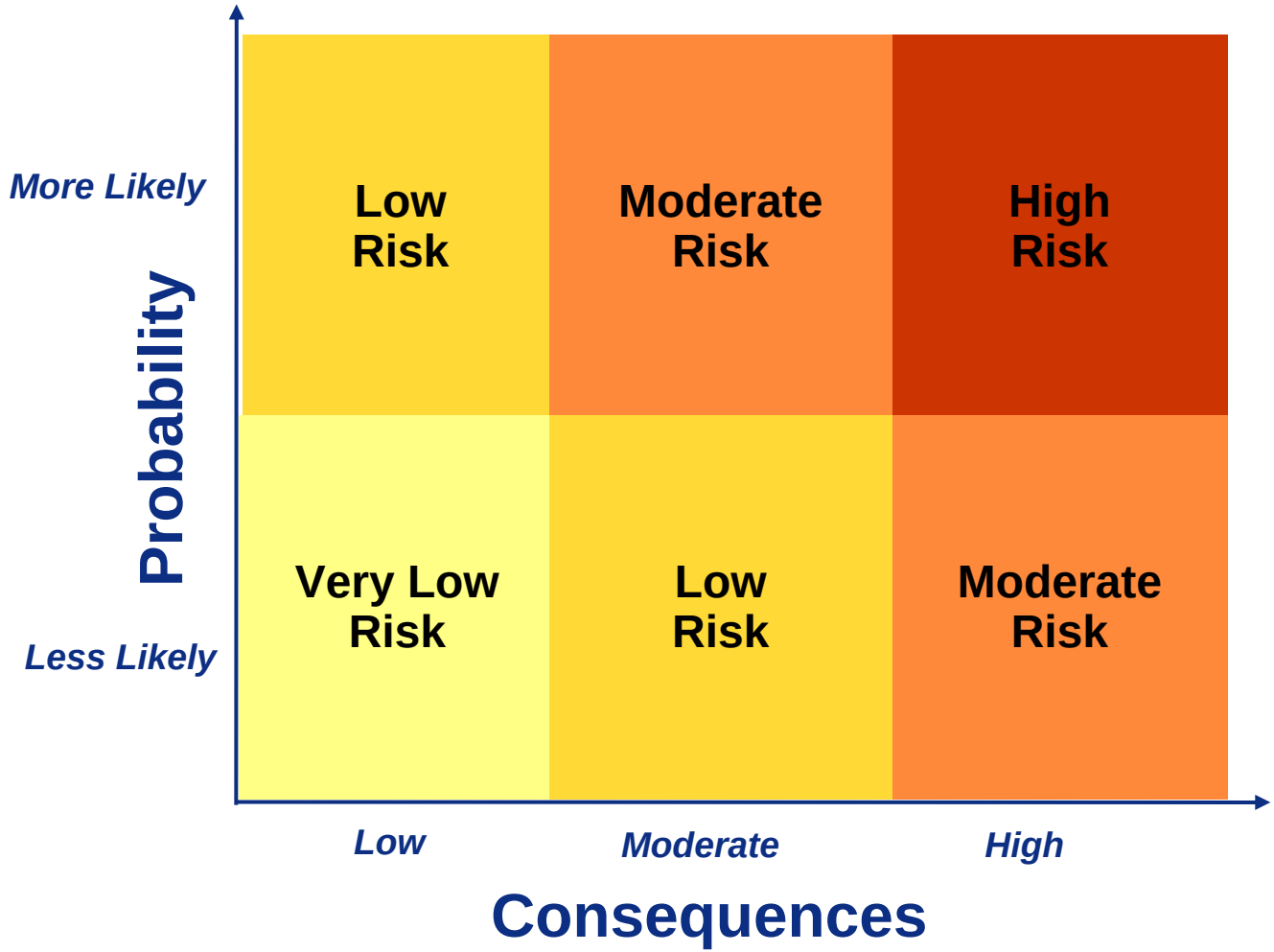
Assess Risk of Threat Scenarios



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Generic Risk Assessment Results

- **High risk scenarios**
  - **Insider, visitor, or outsider with limited access attempting to steal HCPTs covertly**
- **Moderate risk scenarios**
  - **Insider, visitor, or outsider with limited access attempting to steal HCPT-related information covertly**
- **Low risk scenarios**
  - **Small outsider groups that would aim to destroy or deface the facility**
- **Terrorist commando assault unlikely**
  - **Agents available elsewhere**
  - **Overt attack using force would signal authorities to take medical countermeasures**

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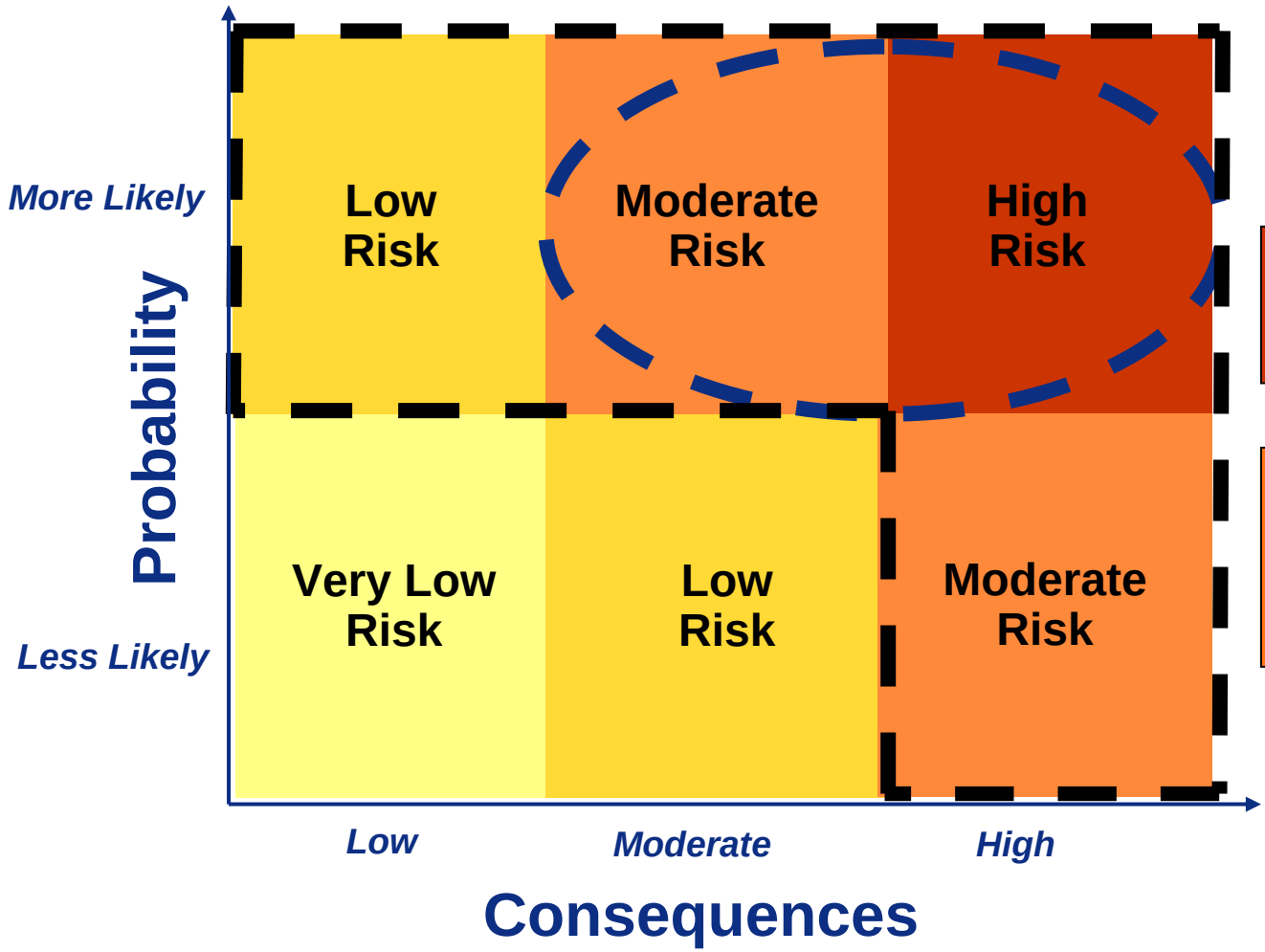
Management Risk Decision



- Protect against unacceptable risk scenarios
- Develop incident response plans for acceptable risk scenarios

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Acceptable and Unacceptable Risks

- This critical decision reflects management's
  - Level of risk tolerance or risk aversion
  - Availability of resources
- Risk assessment is the essential "resource allocation" step

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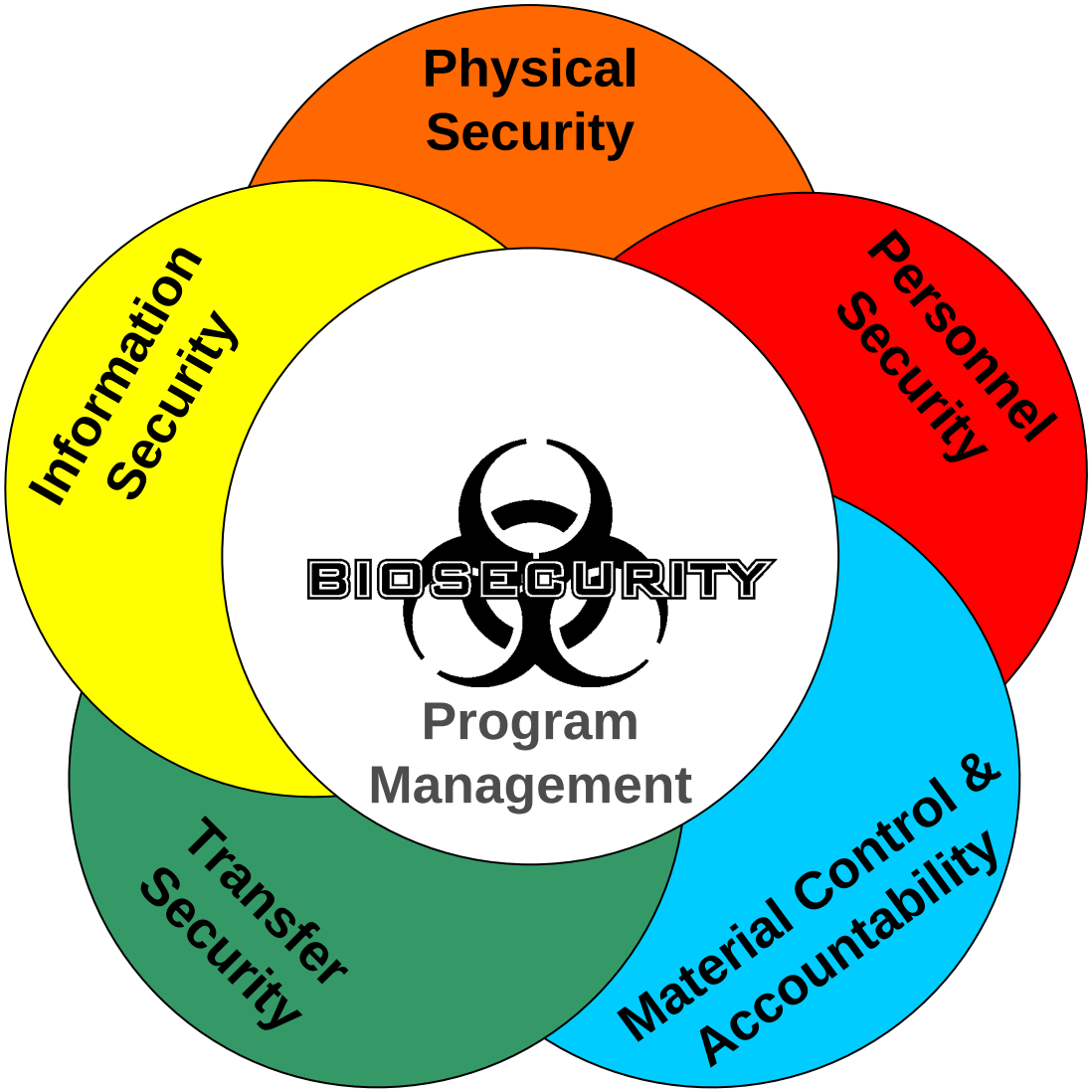
Components of Biosecurity



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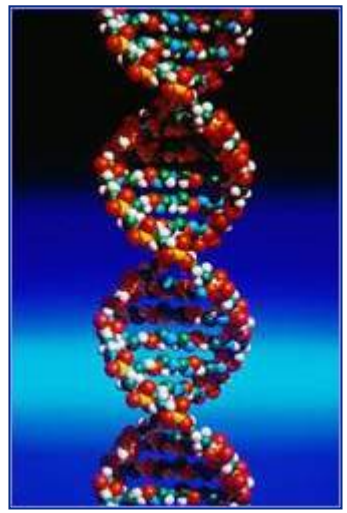
Summary

- Necessary to take steps to reduce the likelihood that HCPTs could be stolen from bioscience facilities
- Critical that these steps are designed specifically for biological materials and research so that the resulting system will balance science and security concerns



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